

Urgent Field Safety Notice

10815622 Rev. A

July 2013

ADVIA Chemistry Systems

A1c_3 Calibrator Positive Bias

Our records indicate that you have or may have received the following product:

Table 1. Table 1- Affected Calibrator

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
A1c_3 Calibrator	10491408	10491408	1MD014 1BD063 2GD014

Reason for Correction

Siemens Healthcare Diagnostics is conducting a field correction for the A1c_3 Calibrator lots listed in Table 1. Siemens has confirmed that the ADVIA® Chemistry Systems HbA1c method exhibits a positive bias of up to 12% for patient and CAP survey samples due to over-recovery when using A1c_3 Calibrator lots 1MD014, 1BD063, and 2GD014. The established ranges of CAP Survey Samples GH2-04, GH2-05 and GH2-06 and IFCC sample recoveries use $\pm 7\%$ from the established mean as their acceptance criteria. This is the criterion that was used during testing to confirm the customer complaints. Depending upon quality control limits this issue may not have been detected. This issue has been corrected beginning with A1c_3 Calibrator lot 2LD017.

Risk to Health

The management of patients with hyperglycemia is dependant upon the monitoring of diet, lifestyle, glucose concentrations and HbA1c. A positive bias of up to 12% in HbA1c may result in modifications of the treatment of hyperglycemia. The modification of hyperglycemic control can increase the risk of occurrence of hypoglycemia which should be observable through symptoms and personal glucose monitoring.

The contents of this communication should be discussed with your Medical Director. A look back should not be required as daily monitoring of glycemic control will mitigate the risk of hypoglycemia.

Siemens Healthcare Diagnostics

511 Benedict Ave.
Tarrytown, NY 10591

www.siemens.com/diagnostics

Page 1 of 3

Actions to be Taken by the Customer

Customers should immediately discard any remaining inventory of the affected lots of A1c_3 Calibrator. Siemens will replace any un-used inventory of the affected lots at no charge.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Technical Solutions Center or your local Siemens technical support representative.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Ref: CHC 13-03

A1c_3 Calibrator Positive Bias

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated July 2013 regarding A1c_3 Calibrator Positive Bias (10815622 Rev. A). Please read each question and indicate the appropriate answer. Fax/Email this completed form to Siemens Healthcare Diagnostics at the fax/email indicated at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in the July 2013 letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Do you now have any of the noted product on hand? (Please check inventories before answering.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. If the answer to the question above is yes, how much product do you have on hand and quantity to be replaced?		
Name of person completing questionnaire: Block Capitals	Date:	

Product Description Product Catalog# / SMN # / Lot #	Quantity Discarded	Replacement Quantity Required

Title:		Instrument Serial Number:	
Hospital:		Street:	
City:		Post Code	
Email		Phone	

**PLEASE FAX THIS COMPLETED FORM TO:
0845-605-6800 or email to robert.davies@siemens.com**